Unverdorben, Martin

To: Marlize De Lange
Subject: RE: (Fwd) 310/2002: Draft Protocol

Martin Unverdorben
MD PhD (E-m...

sorry, there was no attachment

Martin

-----Original Message-----
From: Marlize De Lange [mailto:Marlize.Delange@farmovs-parexel.com]
Sent: Wednesday, January 08, 2003 3:36 AM
To: martin.Unverdorben@pmusa.com
Cc: anina.vanderbijl@farmovs-parexel.com
Subject: (Fwd) 310/2002: Draft Protocol

Dear Martin

A happy new year to you! Thank you for the information on the progression of your discussions regarding the legal issues (your email dated 02 Jan 2003, to Dr Anina).

Did you have any time to review the latest draft version of the protocol for the above mentioned study?

Kind Regards
Marlize
------- Forwarded message follows -------
From: Marlize De Lange <Marlize.Delange@farmovs-parexel.com>
To: martin.Unverdorben@pmusa.com
Subject: 310/2002: Draft Protocol
Copies to: anina.vanderbijl@farmovs-parexel.com, noekie.Rossouw@farmovs-parexel.com
Date sent: Thu, 12 Dec 2002 15:54:45 +0200

Dear Martin

Please find attached the draft protocol with the requested changes as discussed during your telephone conference with Dr Jordaan and Dr van der Bijl. All changes made to the protocol are highlighted in yellow.

There are two outstanding issues:

1). Retention samples: Do you want us to retain unused investigational products as per FDA requirements and if so, for how long?

2). Page 23 of 62 - Identification of Products/Certificates of Analysis:Please provide the necessary information.

We normally send only two draft versions to the sponsor for revision and then provide the final protocol. At this stage no timelines were set. It seems as if there is enough time to consider any further changes, comments and suggestions at your leisure. May we then ask that you provide us with these in "bulk" to enable us to have one final sitting with the protocol before submission to the ethics committee? May we also ask that you send these changes through in electronic form as track changes to the protocol, which will facilitate tremendously in incorporating these

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Source: https://www.industrydocuments.ucsf.edu/docs/xmlj0001

On 9 Jan 2003 at 16:22, Martin.Unverdorben@pmusa.com wrote:

> <?xml:namespace prefix = p ns =
> "urn:schemas-microsoft-com:office:powerpoint" /> Dear All,
>
>
> do you think these timeline may be met?
>
>
> Final Protocol January 2003
> Stress Tests Feb-March 2003
> Data Evaluation May 2003
> Draft Report July 2003
> Final Report September 2003
> Abstract October 2003
> Draft Manuscript December 2003
>
> Regards,
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> Martin
>
>

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Marlize de Lange
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Clinical Research Organisation
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Fax: +27 51 444 3444

PM3005219308

Source: https://www.industrydocuments.ucsf.edu/docs/xmlj0001